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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,684

02/22/2005

David Nickel

9320e

9200

7590 01/23/2008
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EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

01/23/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/525,684

Applicant(s)

NICKEL, DAVID

Examiner

Snigdha Maewall

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 19-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Summary

1. Applicant is reminded that the office has not received IDS as of this date.

Receipt of preliminary amendments and amended claims filed on 02/22/2005 is acknowledged.

Claims **1-14 and 19-22** are pending in this Application. Claims **1-14 and 19-22** will be prosecuted on the merits.

Claim Objection

Claim 4 is objected to because the claim is not further limiting. Examiner suggests reciting "further" after the word blend in claim 4.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "weight percent of any one or mixture of". The

phrase is indefinite as it is unclear whether the limitation is any one or mixture of.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-8 and 10-12 and 19-20 are rejected under 35 U.S.C. 103 (a) as being unpatentable over combinations of the following Patents and Publications:

US Patent No. 6,440,448 (Intelisano et al.) and JP Patent 60207563 A.

Intelisano teaches composition and method using extracts to form compounds as food supplements comprising animal and plant tissue in an orally ingestible carrier such as capsules or any other delivery system (abstract). Example 2 depicts adrenal gland of bovine origin; claim 11 discloses lymphoid mass of bovine origin, bovine pancreas and thymus gland bovine origin. Freeze dried gland was ground (column 4 under 17).

The reference does not teach liver and kidney powder.

JP patent 60207563 teaches preparation comprising kidney powder with other health food materials and processing the mixture into granule and capsule. The kidney powder is prepared by freeze drying and the mixture is filled in to capsules (abstract). Liver powder is also used in the composition (abstract). It would have been obvious to

the one of ordinary skilled in the art at the time the invention was made to incorporate bovine liver and kidney tissues in the composition forwarded by Intelisano because they constitute health food materials. One skilled in the art would have been motivated to prepare a food supplement comprising bovine liver and kidney along with the lymphoid mass of bovine origin, adrenal gland , thymus and pancreas of bovine origin with a reasonable expectation of success. With respect to various amounts of various components claimed, it is the position of the examiner that such parameter can be optimized by doing experimental manipulations. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

6. Claims 9, 13 and 21-22 are rejected under 35 U.S.C. 103 (a) as being unpatentable over the combinations of the following Patents and Publications:
US Patent No. 6,440,448 (Intelisano et al.), Badylak (US Pg pub. 2003/0216812 A1), JP Patent 60207563 A and JP Patent publication (08-173101 by Kagaku KK).

The teachings of Intelisano and JP Patent 60207563 A have been discussed above.

The references do not teach bovine heart tissue and stomach tissue.

Badylak teaches by reference the utility of bovine pericardium and bovine collagen and chondroitin sulfate in paragraph [0017] and Kagaku teaches meat health food product excellent in taste, nutrition and growth promotion comprising placenta and liver of

domestic animals such as bovine, equine, sheep and rabbit and gut of domestic animal in health food preparation (see abstract).

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate bovine internal organs such as heart and stomach tissues in the composition of Intelisano and JP patent 60207563. A skilled artisan would have been motivated to prepare food supplement comprising bovine stomach, liver, kidney , heart and spleen with a reasonable expectation of success since the references collectively teach the importance of bovine internal organs as health food products.

With respect to various amounts of various components claimed, it is the position of the examiner that such parameter can be optimized by doing experimental manipulations. Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

7. Claim 14 is rejected under 35 U.S.C. 103 (a) as being unpatentable over combinations of the following Patents and Publications:

US Patent No. 6,440,448 (Intelisano et al.), JP Patent 60207563 A and Yong et al. (JP publication NO. 2005-104953).

The teachings of Intelisano and JP patent have been discussed above. The references do not teach bone tissue of bovine. Yong teaches use of bovine bones in a composition

for preventing and improving osteoporosis (see title). It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate bone tissues of bovine origin as it helps in treating osteoporosis with a reasonable expectation of success.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information

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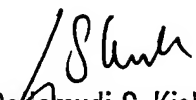
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system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

Art Unit

1612


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